SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR AUXILOCK SHOULDER ARTHROSCOPY SYSTEM

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SRN: IN-MF-000018837

The AUXILOCK Shoulder Arthroscopy System includes the following variants as listed below:

AUXILOCK® Shoulder Arthroscopy system includes Suture Anchor devices. The suture anchors are recommended for use in both large and small joint soft tissue repairs in arthroscopic, mini open or open surgeries. The AC Button can be use in Acromioclavicular joint repair during arthroscopic or open surgeries. There are various types of devices included in the shoulder Arthroscopy system which are as follows:

Titanium Screw-in Anchor with Needle (Basic UDI DI: 08903993SAAT006PJ) **Titanium Screw-in Anchor without Needle** (Basic UDI DI: 08903993SAATN006ZR)

The self-tapping AUXILOCK® Titanium screw-in suture anchor is mostly used as a medial row anchor in rotator cuff repair, Bankart and SLAP surgery. It is recommended for use in small and large-joint repairs without the need for tapping or drilling. AUXILOCK® Titanium screw-in anchors are available in diameter of 2.0mm, 2.5mm, 2.8mm, 3.5mm, 5.0mm and 6.5mm with single, double and triple loaded options. The anchor design incorporates a cancellous thread with a very small core diameter to maximize pull-out strength in cancellous or osteoporotic bone. The anchor design also incorporates a cortical thread to maximize pull-out strength in a cortical or hard bone. The anchor is designed for ultimate mechanical properties (pull-out strength, tensile strength, etc.) and ease-of-use. The anchors are also available with needles which are ideal for mini-open rotator cuff repair procedures. The anchors are also available with needles or without needles which are ideal for mini-open shoulder instability repair procedures.

- AUXILOCK® 2.0mm Titanium Screw-In Suture Anchor With One #0 BioBraid: White/Blue, With Needles
- AUXILOCK® 2.5mm Titanium Screw-In Suture Anchor With One #1 BioBraid: White/Blue, With Needles: MO-6
- AUXILOCK® 2.8mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
- AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
- AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 6.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 5.0mm Twix Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 6.5mm Twix Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 2.0mm Titanium Screw-In Suture Anchor With One #0 BioBraid: White/Blue
- AUXILOCK® 2.5mm Titanium Screw-In Suture Anchor With One #1 BioBraid: White/Blue
- AUXILOCK® 2.8mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue
- AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue
- AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
- AUXILOCK® 6.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black

PEEK OPTIMA Screw In Anchor With Needle (Basic UDI DI: 08903993SAAPON006HU) **PEEK OPTIMA Screw In Anchor Without Needle** (Basic UDI DI: 08903993SAAPO006YL)

AUXILOCK® PEEK OPTIMA Screw-In Suture anchor is a fully threaded suture anchor featuring dual threads to maximize cortical and cancellous fixation. It is available in diameter of 4.5, 5.5 and 6.5mm with double and triple loaded options. It has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly suitable for repairing rotator cuff and associated pathologies. The anchors are available with or without needles which are ideal for mini-open rotator cuff repair procedures.

- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Three #2 BioBraid: White,White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6

PEEK CF Screw In Anchor With Needle (Basic UDI DI: 08903993SAAPCN006DQ) **PEEK CF Screw In Anchor Without Needle** (Basic UDI DI: 08903993SAAPC006VY)

AUXILOCK® PEEK CF Screw-In Anchor is a fully threaded suture anchor featuring dual threads to maximize cortical and cancellous fixation. It is available in 4.5, 5.5 and 6.5mm with double and triple loaded options. It has a flat tip to protect the sutures and to facilitate the insertion. The anchor is particularly

suitable for repairing the rotator cuff and associated pathologies.

- AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Three #2 BioBraid: White,White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
- AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
- AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6

PEEK OPTIMA AuxPik Suture-Based Anchor (Basic UDI DI: 08903993SAAPOS006JX)

AUXILOCK® AuxPik suture-based anchor is made with UHMWPE suture anchor body and PEEK OPTIMA eyelet tip. The anchor is designed to deliver efficiency and promote ease of use. The AuxPik suture-based anchor is available in 1.8mm and 3.2mm diameter with various combination of BioBraid and suture tapes. It can be used for Bankart, SLAP, rotator cuff repair surgeries. The AUXILOCK® AuxPik suture-based anchor provides a small footprint and also asserts subcortical fixation for anchor insertion. The drill guide and anchor driver combination is well-designed to improve the performance and reliability.

- AUXILOCK® 1.8mm AuxPik Suture-Based Anchor With One #2 BioBraid: White/Blue
- AUXILOCK® 1.8mm AuxPik Suture-Based Anchor With One 1.4mm Suture Tape: White/Blue
- AUXILOCK® 3.2mm AuxPik Suture-Based Anchor With Two #2 BioBraid: White/Blue & White/Black

- AUXILOCK® 3.2mm AuxPik Suture-Based Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue

PEEK CF Knotless Anchor with Driver (Basic UDI DI: 08903993SAAPCKD00627) **PEEK CF Knotless Anchor without Driver** (Basic UDI DI: 08903993SAAPCK006D3)

AUXILOCK® knotless push-in anchors provide a step-saving alternative to conventional knotted suture anchors. AUXILOCK® knotless push-in anchors are recommended for use in both large and small-joint soft tissue repairs (i.e. Bankart, SLAP Repair surgeries). PEEK CF Push-In Suture Anchors consists of carbon fibrereinforced PEEK OPTIMA and are available in a variety of diameters of 2.8mm, 3.5mm, 4.5mm and 5.5mm providing intraoperative flexibility. PEEK CF provides modulus of elasticity closely matching the cortical bone. It is non-absorbable, radiolucent, and MRI safe. The knotless technology of Push-in anchor also eliminates knot stacks associated with soft tissue irritation. The anchor is available with and without driver. The 4.5/5.5mm knotless anchor driver is provided separately in the instrument set. It is reusable driver that minimizes the cost of the surgery unlike the pre-loaded suture anchors.

- AUXILOCK® 2.8mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 3.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 4.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 5.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 2.8mm Knotless PEEK CF Push-In Suture Anchor With Hip Length Driver, With Suture Passer
- AUXILOCK® 4.5mm Knotless PEEK CF Push-In Suture Anchor With Suture Passer
- AUXILOCK® 5.5mm Knotless PEEK CF Push-In Suture Anchor With Suture Passer

Rotador PEEK CF Screw In Knotless Anchor (Basic UDI DI: 08903993SAAPCR006EL)

AUXILOCK® ROTADOR PEEK CF Screw-In Anchors are fully threaded knotless anchors available in 4.75, 5.5 and 6.25mm diameters with PEEK CF anchor body and PEEK OPTIMA eyelet. These anchors are designed to be used with sutures or tapes for rotator cuff repair using the 'bridge' techniques. Moreover, the 'knotless' technique consists of passing sutures or tapes of the medial row anchors through the tissue. They are finally inserted into the bone socket once they're loaded through the Rotador anchor eyelet. This technique eliminates possible complications caused by knots compared to other conventional anchors. The eyelet of the anchor accommodates up to 6 sutures and 2 tapes at a time.

- AUXILOCK® Rotador 4.75mm x 15mm PEEK CF Screw-In Anchor

- AUXILOCK® Rotador 5.5mm x 15mm PEEK CF Screw-In Anchor
- AUXILOCK® Rotador 6.25mm x 15mm PEEK CF Screw-In Anchor
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PEEK CF Push In Anchor Without Needle (Basic UDI DI: 08903993SAAPCP006E6) **PEEK CF Push In Anchor with Needle** (Basic UDI DI: 08903993SAAPCPN00664)

AUXILOCK® PEEK CF Push-In Suture Anchor is a Push-in/ Bang-on anchor available in diameter of 2.8 and 3.5mm. It is available in double loaded sutures with and without needle options. The PEEK CF Push-In Suture Anchors are made of carbon fiber-reinforced PEEK-OPTIMA. The PEEK CF provides modulus of elasticity closely matching the cortical bone. It is non-absorbable, radiolucent, and MRI safe. The drill guide and drill bit are provided in the instrument set for the accurate placement of the anchor which minimizes the anchor slippage or breakage during the surgery. Anchor insertion and delivery are made simple by drilling a hole through a drill guide and inserting the anchor through the same drill guide into the drilled hole. The anchor is also available with needles which are ideal for mini-open Bankart or SLAP repair procedures.

- AUXILOCK® 2.8mm PEEK CF Push-In Suture Anchor With One #2 BioBraid: White/Blue
- AUXILOCK® 3.5mm PEEK CF Push-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 2.8mm PEEK CF Push-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6, Short Length
- AUXILOCK® 3.5mm PEEK CF Push-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6, Short Length
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Rotador PEEK OPTIMA Screw In Knotless Anchor (Basic UDI DI: 08903993SAAPOR006JQ)

AUXILOCK® ROTADOR PEEK OPTIMA Screw-In Anchors are fully threaded knotless anchors available in 4.75, 5.5 and 6.25mm diameters with PEEK OPTIMA anchor body and eyelet. These anchors are designed to be used with sutures or tapes for rotator cuff repair using the 'bridge' technique. Moreover, the 'knotless' technique consists of passing sutures or tapes of the medial row anchors through the tissue. They are finally inserted into the bone socket once they're loaded through the Rotador anchor eyelet. This technique eliminates possible complications caused by knots compared to other conventional anchors. The eyelet of the anchor accommodates up to 6 sutures and 2 tapes at a time.

- AUXILOCK® Rotador 4.75mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Rotador 5.5mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Rotador 6.25mm x 15mm PEEK OPTIMA Screw-In Anchor

PEEK OPTIMA Knotless Anchor with Driver (Basic UDI DI: 08903993SAAPOKD00673) **PEEK OPTIMA Knotless Anchor** (Basic UDI DI: 08903993SAAPOK006H7)

AUXILOCK® knotless push-in anchors are a step-saving alternative to conventional knotted suture anchors and are recommended for use in Bankart and SLAP repairs. The PEEK OPTIMA Push-In Suture Anchors are made of PEEK-OPTIMA (Poly-ether-ether-ketone). These Anchors are available in a variety of diameters of 2.8mm, 3.5mm, 4.5mm and 5.5mm providing intraoperative flexibility. The PEEK OPTIMA Push-In Suture Anchor is a one piece body anchor with a material eyelet. It provides superior abrasion resistance due to PEEK's low coefficient friction. It is Biocompatible, radiolucent, and MRI safe. The knotless technology of Push-in anchor also eliminates knot stacks associated with soft tissue irritation.

- AUXILOCK® 2.8mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 3.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 4.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 5.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
- AUXILOCK® 2.8mm Knotless PEEK OPTIMA Push-In Suture Anchor With Hip Length Driver, With Suture Passer
- AUXILOCK® 4.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Suture Passer
- AUXILOCK® 5.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Suture Passer

PEEK OPTIMA Push In Anchor without Needle (Basic UDI DI: 08903993SAAPOP006JA) **PEEK OPTIMA Push In Anchor with Needle** (Basic UDI DI: 08903993SAAPOPN006AY)

AUXILOCK® PEEK OPTIMA Push-In Suture Anchor is a Push-in/ Bang-on anchor available in diameter of 2.8 and 3.5mm. It is available in double loaded sutures with and without needle options. The PEEK OPTIMA Push-In Suture Anchors are made of PEEK-OPTIMA (Poly-ether-etherketone). The PEEK OPTIMA Push-In Suture Anchors are non-absorbable PEEK suture anchors with a material eyelet. It provides superior abrasion resistance due to PEEK's low coefficient friction. It is considered to be Biocompatible, radiolucent, and MRI safe. The drill guide and the
drill bit are provided in the instrument set for an accurate placement of the anchor which minimizes the anchor slippage or breakage during the surgery. Anchor insertion and delivery are made simple by drilling a hole through a drill guide and inserting the anchor through the same
drill guide into the drilled hole.

- AUXILOCK® 2.8mm PEEK OPTIMA Push-In Suture Anchor With One #2 BioBraid: White/Black
- AUXILOCK® 3.5mm PEEK OPTIMA Push-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
- AUXILOCK® 2.8mm PEEK OPTIMA Push-In Suture Anchor With One #2 BioBraid: White/Black, With Needles: MO-6, Short Length
- AUXILOCK® 3.5mm PEEK OPTIMA Push-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6, Short Length

Auxsuture Anchor without Needle (Basic UDI DI: 08903993SAAU006PR) **Auxsuture Anchor with Needle** (Basic UDI DI: 08903993SAAUN00627)
AUXILOCK® AuxSuture Anchor Provides numerous advantages over traditional anchors for shoulder instability repair, rotator cuff repair procedures with its strong fixations, less bone removal and a push in techniques. AuxSuture anchor is available in diameter of 1.2mm, 1.5mm, 1.8mm and 2.9mm. It is available in single and double loaded options with various combination of BioBraid and suture tapes. The drill guide and 2.9mm Awl, 1.5mm drill bit are specially designed for AuxSuture Anchor while assuming an accurate hole placement for the anchor. The small 1.5mm footprint AuxSuture anchor provides placement and fixation advantages when bone real estate is limited, especially during revision surgeries. The anchor is available with or without needles which are ideal for mini-open surgeries.

- AUXILOCK® 1.2mm AuxSuture Anchor With One #0 BioBraid: White/Blue
- AUXILOCK® 1.2mm AuxSuture Anchor With One #0 BioBraid: White/Blue, With Needles
- AUXILOCK® 1.5mm AuxSuture Anchor With One #2 BioBraid: White/Blue
- AUXILOCK® 1.5mm AuxSuture Anchor With One 1.4mm Suture Tape: White/Blue
- AUXILOCK® 1.8mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green
- AUXILOCK® 1.8mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 2.9mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green
- AUXILOCK® 2.9mm AuxSuture Anchor With Three #2 BioBraid: White, White/Blue & White/Green
- AUXILOCK® 2.9mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 2.9mm AuxSuture Anchor With Two 1.4mm Suture Tape: White/Black & White/Blue
- AUXILOCK® 1.5mm AuxSuture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
- AUXILOCK® 1.8mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green, With Needles: MO-6
- AUXILOCK® 1.8mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue, With Needles: MO-6

- AUXILOCK® 2.9mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green, With Needles: MO-6

PEEK OPTIMA Tendo Screw-In Anchor (Basic UDI DI: 08903993SAAPOT006K6)

AUXILOCK® Tendo PEEK OPTIMA Screw-In Anchor is ideal for proximal biceps tenodesis repair. It is available in 7.0, 8.0 and 9.0mm diameters with PEEK OPTIMA interference/tenodesis screw and PEEK OPTIMA Washer. The Eyelet is specifically designed to hold the biceps tendon at the bottom of the drill hole. After fixing up the tendon into the drill hole, it can be locked into the bone by advancing the tenodesis screw. The anchor is designed to save steps and minimize the length of the procedure.

- AUXILOCK® Tendo 7.0mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Tendo 8.0mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Tendo 9.0mm x 15mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Tendo 7.0mm x 10mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Tendo 8.0mm x 10mm PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Tendo 9.0mm x 10mm PEEK OPTIMA Screw-In Anchor

PEEK CF Tendo Screw-In Anchor (Basic UDI DI: 08903993SAAPCT006F2)

AUXILOCK® Tendo PEEK CF Screw-In Anchor is ideal for proximal biceps tenodesis repair. It is available in 7.0, 8.0 and 9.0mm diameters with PEEK CF interference/tenodesis screw and PEEK OPTIMA washer. The Eyelet is specifically designed to hold the biceps tendon at the bottom of the drill hole. After fixing up the tendon into the drill hole, it can be locked into the bone by advancing the tenodesis screw. The anchor is designed to save steps and minimize the length of the procedure.

- AUXILOCK® Tendo 7.0mm x 15mm PEEK CF Screw-In Anchor
- AUXILOCK® Tendo 8.0mm x 15mm PEEK CF Screw-In Anchor
- AUXILOCK® Tendo 9.0mm x 15mm PEEK CF Screw-In Anchor
- AUXILOCK® Tendo 7.0mm x 10mm PEEK CF Screw-In Anchor
- AUXILOCK® Tendo 8.0mm x 10mm PEEK CF Screw-In Anchor
- AUXILOCK® Tendo 9.0mm x 10mm PEEK CF Screw-In Anchor

AC Joint Button (Basic UDI DI: 08903993SABT006PV)

AUXILOCK® AC Joint Kit can be used for Acromioclavicular Joint (AC Joint) separation repair. The kit comprises of adjustable loop with round shaped button (Dia. 5.5mm) and oblong shaped button (L 12mm X W 3.2mm X H 1.5mm). A tunnel is made through the clavicle and coracoid using 1.5mm K-Wire and 3.5mm Cannulated Drill Bit. The kit is passed through 3.5mm drilling tunnel from clavicle to coracoid provides the fixation of round button on the clavicle and oblong shaped button on the coracoid. The AC Joint Kit provides a double locking mechanism which eliminates the need for knot tying and also provides very strong compression on the clavicles.

AUXILOCK® AuxFix Button is a titanium button with holes that allow use of multiple suture tapes for AC joint reduction. It provides very strong compression on the clavicles. The button is laid on the outer surface of the clavicle or the underneath the coracoid. Only the suture material is passed through the clavicle and coracoid tunnel ensuring minimal bone loss during the procedures.

- AUXILOCK® AuxFix Button (AC Joint)
- AUXILOCK® AC Joint Kit

Gyrolock PEEK OPTIMA Knotless Screw In Anchor (Basic UDI DI: 08903993SAAPOG006GB) **Gyrolock SP PEEK OPTIMA Knotless Screw In Anchor** (Basic UDI DI: 08903993SAAPOGS0068Y)

GyroLock Knotless PEEK OPTIMA Screw-in Anchors consists of PEEK-OPTIMA (Poly-ether-ether-ketone) material. The GyroLock suture anchor comes with Dual start thread technology (fast inserting suture anchor) which allows anchor deployment in 3.5 rotation. Vented and cannulated GyroLock anchors are designed for repair and reconstruction with soft-tissue graft. GyroLock anchor is available with multiple BioBraid suture and suture tape configurations. GyroLock suture anchor eyelet can accommodate up to four 1.4mm tapes or four #2 sutures.

- AUXILOCK® Gyrolock 3.5mm x 15.8mm Knotless PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Gyrolock 4.75mm x 22.5mm Knotless PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Gyrolock 5.5mm x 22.5mm Knotless PEEK OPTIMA Screw-In Anchor
- AUXILOCK® Gyrolock SP 4.75mm x 24.5mm Knotless PEEK OPTIMA Screw-In Anchor, Self-Punching
- AUXILOCK® Gyrolock SP 5.5mm x 24.5mm Knotless PEEK OPTIMA Screw-In Anchor, Self-Punching

Details Regarding the device are provided in below table:

Device Trade Name:	**AUXILOCK Shoulder Arthroscopy System**		
Manufacturer Details	**Name & Address of Manufacturer:** Auxein Medical Pvt. Ltd. **Manufacturing Unit:** Plot No. 168-169-170, Phase IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonipat, Haryana– 131028, India **Phone:** +91-9910643638 **Email: info@auxeinmedical.com** **Website: www.auxein.com**		
Manufacturer's SRN	IN-MF-000018837		
Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, AUXILOCK Shoulder Arthroscopy System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000434275-PA-NA-IND Rev. 0.0
Year when the first certificate (CE) was issued covering the device	2021		
Raw Materials of Implants	The Raw Materials used for manufacturing the Implants consists of Titanium Alloy (Ti-6Al-4V) as per ISO 5832-3:2021, PEEK OPTIMA as per ASTM F2026 and PEEK CF as per ASTM F3333, Stainless Steel as per ISO 7153-1:2016 and UHMWPE Yarn/Suture (BioBraid) as per ASTM F2848.		
USFDA Cleared	Yes (AUXILOCK Shoulder Arthroscopy System are approved by USFDA whose details are as follow:) **510(k) Number:** K213110, K213109, K213104		
Conformity Assessment Route	Conformity Assessment of Class IIb devices has been conducted as per Article 52 (4), Chapter I, II and III of Annex IX of EU MDR 2017/745.		
EMDN Code	P09120102		
Risk Class	IIb {According to REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT, Annex VIII, Chapter-3, Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)} are in Class IIb unless they are intended:		

1. Are intended to be placed in the teeth, in which case they are classified as class IIa;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Shoulder Arthroscopy System intended to be placed in Shoulder joint to fix the muscle, tendon and ligaments.

2. Are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Shoulder Arthroscopy System comes in contact with the Shoulder joint. Thus, it does not come in contact with the heart, the central circulatory system or the central nervous system.

3. Have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Shoulder Arthroscopy System is made up of medical grade metallic alloy and Polymer. Metallic alloy/Polymer does not achieve its intended use by biological effect or by absorption.

4. Are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Shoulder Arthroscopy System is made up of medical grade metallic elements/polymers. These metallic element/polymer have high metallic bonds that do not undergo chemical change in the body.

5. Are intended to administer medicinal products, in which case they are classified as class III;

Applicable/ Not Applicable: Not Applicable

Justification: The AUXILOCK Shoulder Arthroscopy System implants made up of metal alloys/polymer to provide fixation for the repair of muscle, tendon and ligaments. The system is not intended to administer medicinal products.

6. Are active implantable devices or their accessories, in which cases they are classified as class III;
Applicable/ Not Applicable: Not Applicable
Justification: The AUXILOCK Shoulder Arthroscopy System does not depend on a source of energy. Thus it is not an active device.

7. Are breast implants or surgical meshes, in which cases they are classified as class III;
Applicable/ Not Applicable: Not Applicable
Justification: The AUXILOCK Shoulder Arthroscopy System fix the muscle, ligament and tendon rupture. Not intended as breast implants or surgical meshes.

8. Are total or partial joint replacements, in which case they are classified as class III, except ancillary components such as screws, wedges, plates and instruments; or;
Applicable/ Not Applicable: Not Applicable
Justification: The AUXILOCK Shoulder Arthroscopy System fix the muscle, tendon and ligaments.. Not intended for Total or Partial Joint Replacements.

9. Are Spinal Disc Replacement Implants or are implantable devices that come into contact with the Spinal Column, in which case they are classified as class III except components such as screws, wedges, plates and instruments:
Applicable/ Not Applicable: Not Applicable
Justification: The AUXILOCK Shoulder Arthroscopy System is an implantable device to fix the muscle, tendon and ligaments. The AUXILOCK Shoulder Arthroscopy System is not recommended for the Spinal Disc Replacement Implants and do not come into contact with the spinal column.

Authorized Representative Name and Address	**Name:** CMC Medical Devices & Drug S.L **Address:** 29015 Málaga, Spain
Authorized Representative SRN	ES-AR-00000029
Notified Body Name and Single Identification Number	**Name:** DNV Product Assurance AS **Single Identification Number:** 2460

2. The intended purpose of the device and any indications, contraindications and target populations.

The Indications, Contraindication and Intended Patient Population related information is provided in below table:

Indications of Use	The AUXILOCK Shoulder Arthroscopy System is indicated for use in Bankart lesion repairs, SLAP lesion repairs, Acromioclavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsulolabral reconstructions, Biceps tenodesis, and Deltoid Repairs.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: Any case not described in the indications.In patients where there is a possibility for conservative treatment.Active, suspected or latent infection in the affected area.SepsisInsufficient quantity or quality of bone, osteoporosisBlood supply limitations or other systemic conditions that may retard healing.Fever or leukocytosis.Foreign body sensitivity, if suspected.
Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
Intended Users	The AUXILOCK Shoulder Arthroscopy Systems are to be used by well experienced, qualified & specialized trained surgeons only.
Category	Non-Active, Implantable, Long term, Surgically Invasive Device.
Use	For Single Use only
Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
Biocompatibility	The devices covered in the AUXILOCK Shoulder Arthroscopy System are Bio-compatible. Biocompatibility of the devices is tested as per EN ISO 10993-1:2020 series of International Standard.

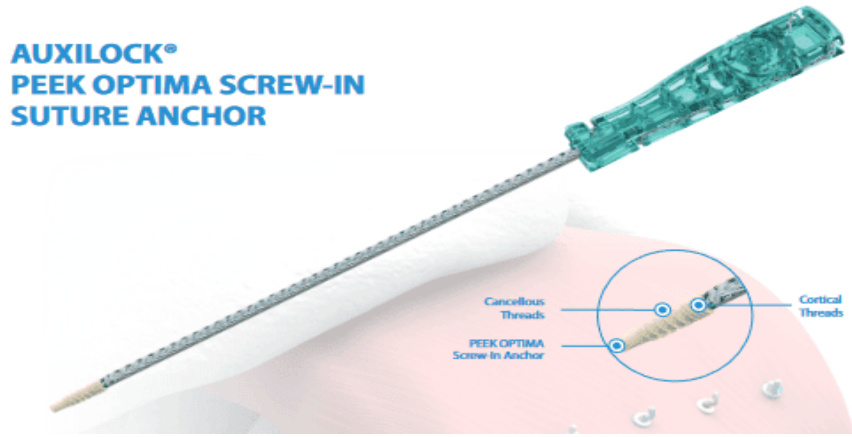
3. Description of the device

PRODUCT STRUCTURE, MATERIAL & SPECIFICATION

Titanium Screw-In Anchor		
S. No.	Device Name	Titanium Screw-In Anchor with Needle, Titanium Screw-In Anchor without Needle
1, 2.	Picture	
	Code	Product Description
		Titanium Screw In Anchor With Needle
	6-005-11	AUXILOCK® 2.0mm Titanium Screw-In Suture Anchor With One #0 BioBraid: White/Blue, With Needles
	6-005-12	AUXILOCK® 2.5mm Titanium Screw-In Suture Anchor With One #1 BioBraid: White/Blue, With Needles: MO-6
	6-005-05	AUXILOCK® 2.8mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
	6-005-13	AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
	6-005-06	AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-004-05	AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles:

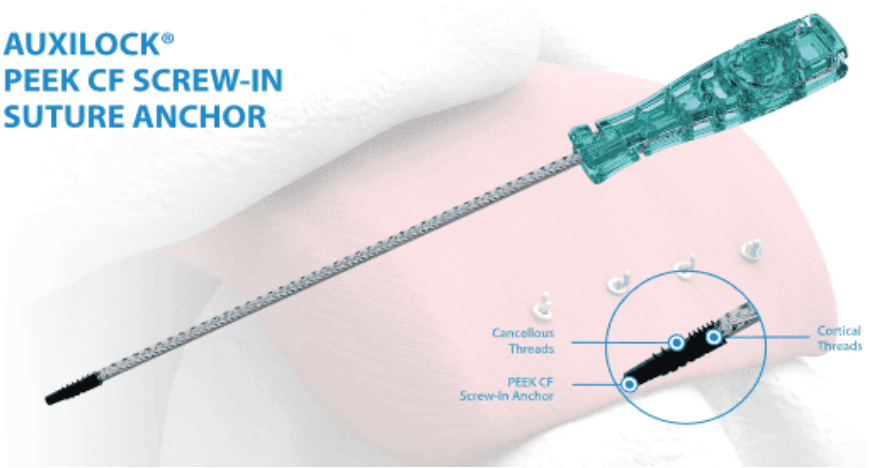
		MO-6
	6-004-06	AUXILOCK® 6.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-045-01	AUXILOCK® 5.0mm Twix Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-045-02	AUXILOCK® 6.5mm Twix Titanium Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
		Titanium Screw In Anchor Without Needle
	6-005-16	AUXILOCK® 2.0mm Titanium Screw-In Suture Anchor With One #0 BioBraid: White/Blue
	6-005-15	AUXILOCK® 2.5mm Titanium Screw-In Suture Anchor With One #1 BioBraid: White/Blue
	6-005-01	AUXILOCK® 2.8mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue
	6-005-14	AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With One #2 BioBraid: White/Blue
	6-005-02	AUXILOCK® 3.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-004-02	AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-004-13	AUXILOCK® 5.0mm Titanium Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
	6-004-04	AUXILOCK® 6.5mm Titanium Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	Raw Material	Titanium Alloy as per EN ISO 5832-3/ASTM F136, UHMWPE Suture as per ASTM F2848 and Stainless Steel Needle as per ISO 7153-1:2016/ASTM F899

PEEK OPTIMA Screw In Anchor		
S. No.	Device Name	PEEK OPTIMA Screw In Anchor With Needle, PEEK OPTIMA Screw In Anchor Without Needle

3, 4.	Picture	
	Code	Product Description
		PEEK OPTIMA Screw In Anchor Without Needle
	6-016-05	AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-016-07	AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-016-08	AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-016-13	AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
	6-016-14	AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Three #2 BioBraid: White,White/Blue & White/Black
	6-016-15	AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black

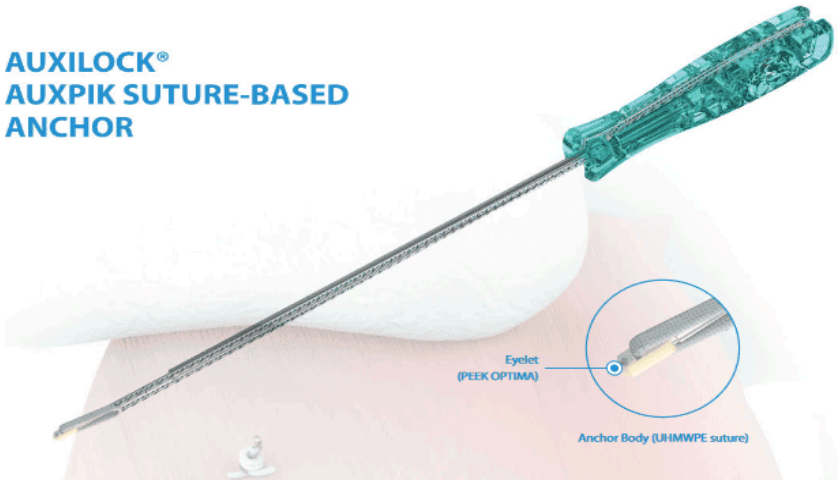
	6-016-16	AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black
	6-016-17	AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Blue & White/Black
	6-016-18	AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
	6-016-19	AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
	6-016-20	AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
		PEEK OPTIMA Screw In Anchor With Needle
	6-016-01	AUXILOCK® 4.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-016-03	AUXILOCK® 5.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-016-04	AUXILOCK® 6.5mm PEEK OPTIMA Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	Raw Material	PEEK OPTIMA as per ASTM F2026 and UHMWPE Suture as per ASTM F2848 and Stainless Steel needle as per ISO 7153-1:2016/ASTM F899

PEEK CF Screw In Anchor		
S. No.	Device Name	PEEK CF Screw In Anchor With Needle, PEEK CF Screw In Anchor Without Needle

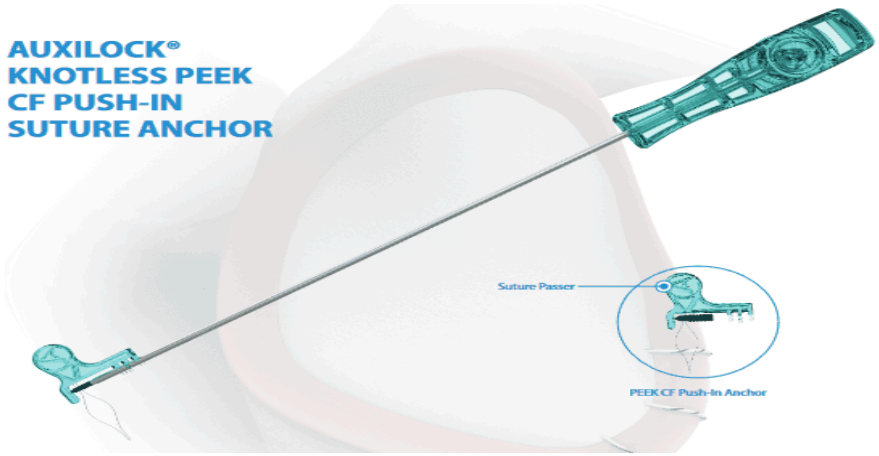
5, 6.	Picture	
	Code	Product Description
		PEEK CF Screw In Anchor Without Needle
	6-046-01	AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Three #2 BioBraid: White, White/Blue & White/Black
	6-046-02	AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-046-03	AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Three #2 BioBraid: White,White/Blue & White/Black
	6-046-04	AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-046-05	AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-046-06	AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue

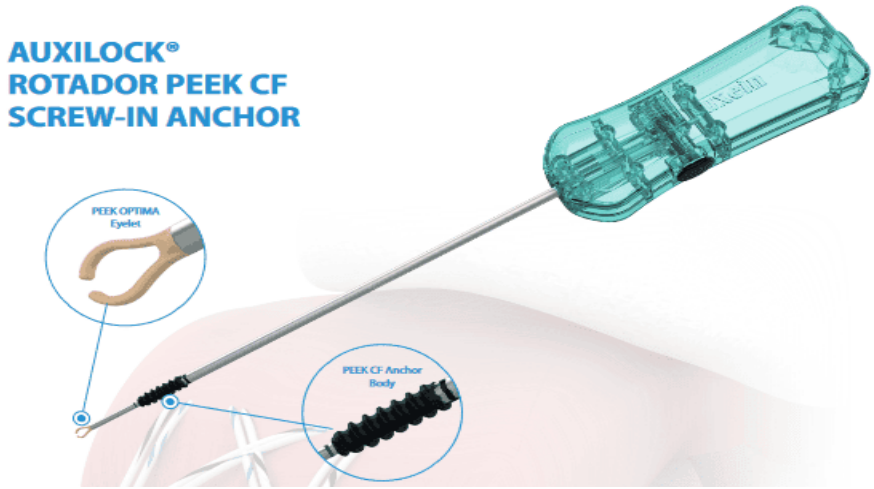
	6-046-07	AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
	6-046-08	AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
	6-046-09	AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
	6-046-10	AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
	6-046-11	AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two 1.4mm Suture Tape: White/Blue & White/Black
		PEEK CF Screw In Anchor With Needle
	6-016-21	AUXILOCK® 4.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-016-22	AUXILOCK® 5.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	6-016-23	AUXILOCK® 6.5mm PEEK CF Screw-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6
	Raw Material	PEEK CF as per ASTM F3333, UHMWPE Suture as per ASTM F2848 and Stainless Steel Needle as per ISO 7153-1:2016/ASTM F899

PEEK OPTIMA AuxPik Suture-Based Anchor		
S. No.	Device Name	PEEK OPTIMA AuxPik Suture-Based Anchor

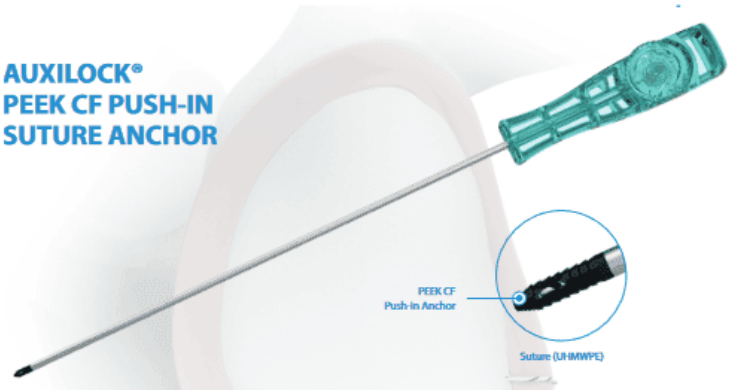
7.	Picture	
	Code	Product Description
	6-001-01	AUXILOCK® 1.8mm AuxPik Suture-Based Anchor With One #2 BioBraid: White/Blue
	6-001-03	AUXILOCK® 3.2mm AuxPik Suture-Based Anchor With Two #2 BioBraid: White/Blue & White/Black
	6-001-08	AUXILOCK® 1.8mm AuxPik Suture-Based Anchor With One 1.4mm Suture Tape: White/Blue
	6-001-09	AUXILOCK® 3.2mm AuxPik Suture-Based Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
	Raw Material	PEEK OPTIMA as ASTM F2026 and UHMWPE Suture as per ASTM F2848.

PEEK CF Knotless Anchor		
S. No.	Device Name	PEEK CF Knotless Anchor with Driver, PEEK CF Knotless Anchor without Driver

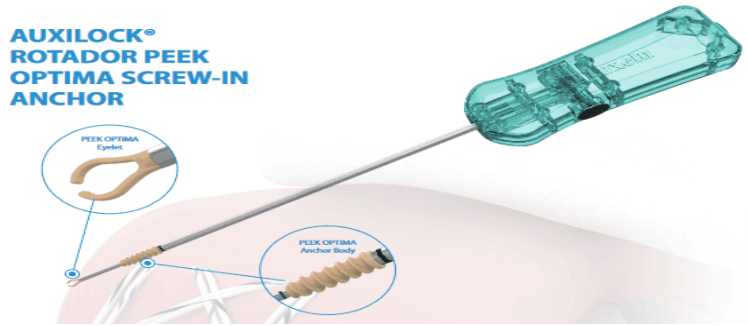
8, 9.	Picture	
	Code	Product Description
		PEEK CF Knotless Anchor With Driver
	6-003-01	AUXILOCK® 2.8mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
	6-003-02	AUXILOCK® 3.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
	6-003-14	AUXILOCK® 4.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
	6-003-15	AUXILOCK® 5.5mm Knotless PEEK CF Push-In Suture Anchor With Driver, With Suture Passer
	6-038-02	AUXILOCK® 2.8mm Knotless PEEK CF Push-In Suture Anchor With Hip Length Driver, With Suture Passer (Hip)
		PEEK CF Knotless Anchor without Driver
	6-003-04	AUXILOCK® 4.5mm Knotless PEEK CF Push-In Suture Anchor With Suture Passer
	6-003-05	AUXILOCK® 5.5mm Knotless PEEK CF Push-In Suture Anchor With Suture Passer
	Raw Material	PEEK CF as per ASTM F3333 and UHMWPE Suture as per ASTM F2848.

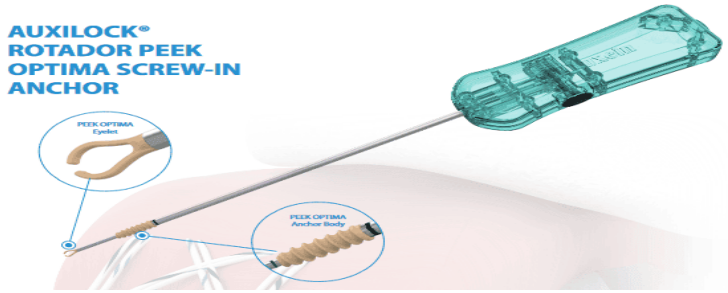
Rotador PEEK CF Screw In Knotless Anchor		
S. No.	Device Name	Rotador PEEK CF Screw In Knotless Anchor
10.	Picture	
	Code	Product Description
	6-020-04	AUXILOCK® Rotador 4.75mm x 15mm PEEK CF Screw-In Anchor
	6-020-05	AUXILOCK® Rotador 5.5mm x 15mm PEEK CF Screw-In Anchor
	6-020-06	AUXILOCK® Rotador 6.25mm x 15mm PEEK CF Screw-In Anchor
	Raw Material	PEEK CF as per ASTM F3333 and UHMWPE Suture as per ASTM F2848.

PEEK CF Push In Anchor		
S. No.	Device Name	PEEK CF Push In Anchor Without Needle, PEEK CF Push In Anchor with Needle

11, 12.	Picture	
	Code	Product Description
		PEEK CF Push In Anchor Without Needle
	6-002-06	AUXILOCK® 2.8mm PEEK CF Push-In Suture Anchor With One #2 BioBraid: White/Blue
	6-002-01	AUXILOCK® 3.5mm PEEK CF Push-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
		PEEK CF Push In Anchor With Needle
	6-002-07	AUXILOCK® 2.8mm PEEK CF Push-In Suture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6, Short Length
	6-002-02	AUXILOCK® 3.5mm PEEK CF Push-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6, Short Length
	Raw Material	PEEK CF as per ASTM F3333, UHMWPE Suture as per ASTM F2848, Needle as per ISO 7153-1:2016/ASTM F899.

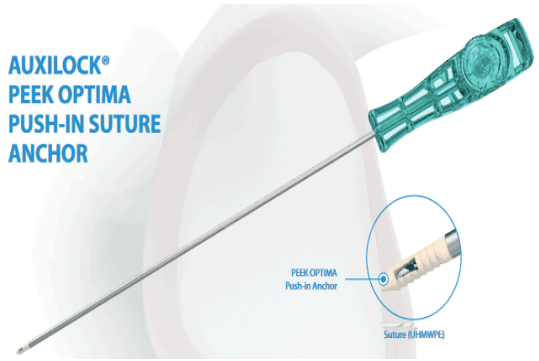
Rotador PEEK OPTIMA Screw In Knotless Anchor		
S.No.	Device Name	Rotador PEEK OPTIMA Screw In Knotless Anchor

13.	Picture	
	Code	Product Description
	6-020-01	AUXILOCK® Rotador 4.75mm x 15mm PEEK OPTIMA Screw-In Anchor
	6-020-02	AUXILOCK® Rotador 5.5mm x 15mm PEEK OPTIMA Screw-In Anchor
	6-020-03	AUXILOCK® Rotador 6.25mm x 15mm PEEK OPTIMA Screw-In Anchor
	Raw Material Specification	PEEK OPTIMA as per ASTM F2026 and UHMWPE Suture as per ASTM F2848.

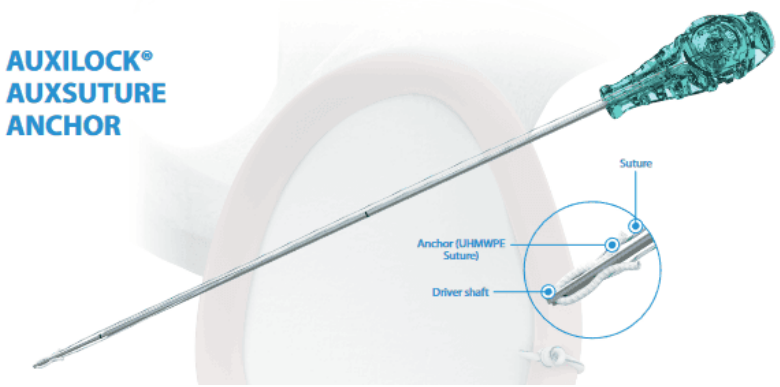
PEEK OPTIMA Knotless Anchor		
S.No.	Device Name	PEEK OPTIMA Knotless Anchor with Driver, PEEK OPTIMA Knotless Anchor
14.	Picture	

	Code	Product Description
		PEEK OPTIMA Knotless Anchor With Driver
	6-031-01	AUXILOCK® 2.8mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
	6-031-02	AUXILOCK® 3.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
	6-031-07	AUXILOCK® 4.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
	6-031-08	AUXILOCK® 5.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Driver, With Suture Passer
	6-039-02	AUXILOCK® 2.8mm Knotless PEEK OPTIMA Push-In Suture Anchor With Hip Length Driver, With Suture Passer (Hip)
		PEEK OPTIMA Knotless Anchor
	6-031-04	AUXILOCK® 4.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Suture Passer
	6-031-05	AUXILOCK® 5.5mm Knotless PEEK OPTIMA Push-In Suture Anchor With Suture Passer
	Raw Material Specification	PEEK OPTIMA as per ASTM F2026, UHWMPE Suture as per ASTM F2848.

PEEK OPTIMA Push In Anchor

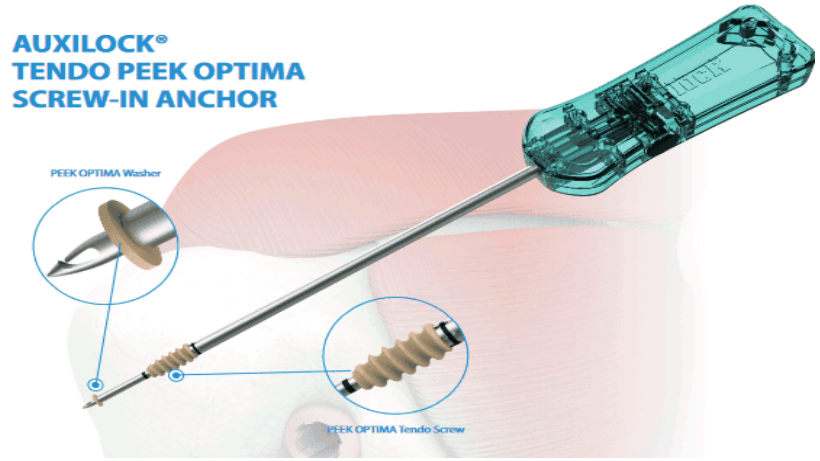
S.No.	Device Name	PEEK OPTIMA Push In Anchor without Needle, PEEK OPTIMA Push In Anchor with Needle
15, 16	Picture	
	Code	Product Description
		PEEK OPTIMA Push In Anchor Without Needle
	6-030-03	AUXILOCK® 2.8mm PEEK OPTIMA Push-In Suture Anchor With One #2 BioBraid: White/Black
	6-030-01	AUXILOCK® 3.5mm PEEK OPTIMA Push-In Suture Anchor With Two #2 BioBraid: White/Blue & White/Black
		PEEK OPTIMA Push In Anchor With Needle
	6-030-04	AUXILOCK® 2.8mm PEEK OPTIMA Push-In Suture Anchor With One #2 BioBraid: White/Black, With Needles: MO-6, Short Length
	6-030-02	AUXILOCK® 3.5mm PEEK OPTIMA Push-In Suture Anchor With Two #2 BioBraid: White & White/Blue, With Needles: MO-6, Short Length
	Raw Material Specification	PEEK OPTIMA as per ASTM F2026, UHMWPE Suture as per ASTM F2848 and Stainless Steel

		Needle as per ISO 7153-1:2016/ASTM F899

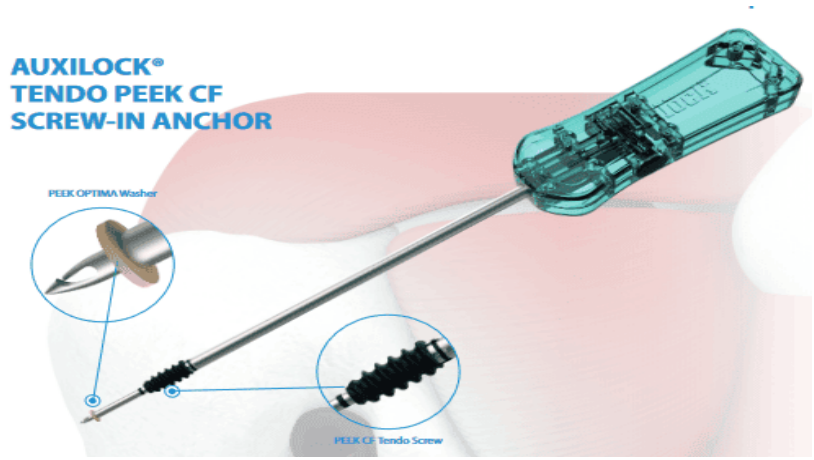
Auxsuture Anchor		
S.No.	Device Name	Auxsuture Anchor without Needle, Auxsuture Anchor with Needle
17, 18.	Picture	
	Code	Product Description
		(All) AuxSuture Anchor Without Needle
	6-040-01	AUXILOCK® 1.2mm AuxSuture Anchor With One #0 BioBraid: White/Blue
	6-040-02	AUXILOCK® 1.2mm AuxSuture Anchor With One #0 BioBraid: White/Blue, With Needles
	6-034-01	AUXILOCK® 1.5mm AuxSuture Anchor With One #2 BioBraid: White/Blue
	6-034-02	AUXILOCK® 1.5mm AuxSuture Anchor With One 1.4mm Suture Tape: White/Blue
	6-035-01	AUXILOCK® 1.8mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green
	6-035-02	AUXILOCK® 1.8mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue

6-036-01	AUXILOCK® 2.9mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green
6-036-03	AUXILOCK® 2.9mm AuxSuture Anchor With Three #2 BioBraid: White, White/Blue & White/Green
6-036-04	AUXILOCK® 2.9mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue
6-036-05	AUXILOCK® 2.9mm AuxSuture Anchor With Two 1.4mm Suture Tape: White/Black & White/Blue
	(All) AuxSuture Anchor With Needle
6-034-03	AUXILOCK® 1.5mm AuxSuture Anchor With One #2 BioBraid: White/Blue, With Needles: MO-6
6-035-03	AUXILOCK® 1.8mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green, With Needles: MO-6
6-035-04	AUXILOCK® 1.8mm AuxSuture Anchor With One #2 BioBraid and One 1.4mm Suture Tape: White/Black & White/Blue, With Needles: MO-6
6-036-02	AUXILOCK® 2.9mm AuxSuture Anchor With Two #2 BioBraid: White/Blue & White/Green, With Needles: MO-6
Raw Material Specification	UHMWPE Suture as per ASTM F2848 and Stainless Steel Needle and per ISO 7153-1:2016/ASTM F899

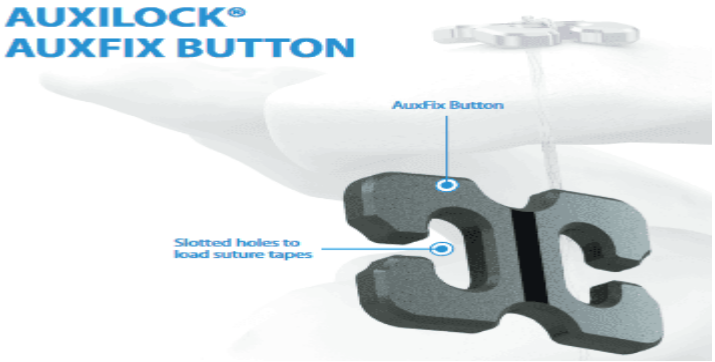
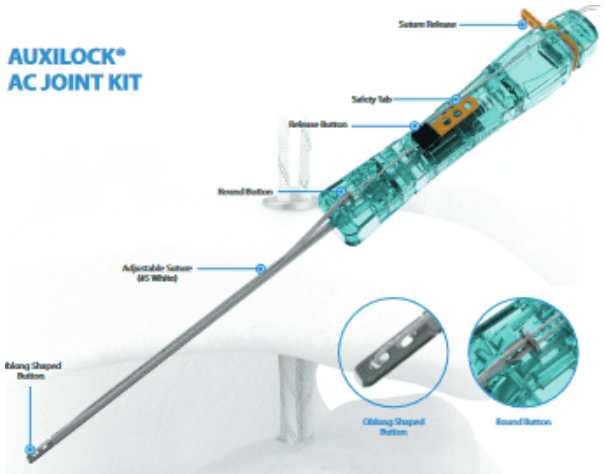
PEEK OPTIMA Tendo Screw-In Anchor		
S. No.	Device Name	PEEK OPTIMA Tendo Screw-In Anchor

19.	Picture	
	Code	Product Description
	6-042-01	AUXILOCK® Tendo 7.0mm x 15mm PEEK OPTIMA Screw-In Anchor
	6-042-02	AUXILOCK® Tendo 8.0mm x 15mm PEEK OPTIMA Screw-In Anchor
	6-042-03	AUXILOCK® Tendo 9.0mm x 15mm PEEK OPTIMA Screw-In Anchor
	6-042-04	AUXILOCK® Tendo 7.0mm x 10mm PEEK OPTIMA Screw-In Anchor
	6-042-05	AUXILOCK® Tendo 8.0mm x 10mm PEEK OPTIMA Screw-In Anchor
	6-042-06	AUXILOCK® Tendo 9.0mm x 10mm PEEK OPTIMA Screw-In Anchor
	Raw Material	PEEK OPTIMA as per ASTM F2026 and UHMWPE Suture as per ASTM F2848.

PEEK CF Tendo Screw-In Anchor		
S. No.	Device Name	PEEK CF Tendo Screw-In Anchor

20.	Picture	
	Code	Product Description
	6-043-01	AUXILOCK® Tendo 7.0mm x 15mm PEEK CF Screw-In Anchor
	6-043-02	AUXILOCK® Tendo 8.0mm x 15mm PEEK CF Screw-In Anchor
	6-043-03	AUXILOCK® Tendo 9.0mm x 15mm PEEK CF Screw-In Anchor
	6-043-04	AUXILOCK® Tendo 7.0mm x 10mm PEEK CF Screw-In Anchor
	6-043-05	AUXILOCK® Tendo 8.0mm x 10mm PEEK CF Screw-In Anchor
	6-043-06	AUXILOCK® Tendo 9.0mm x 10mm PEEK CF Screw-In Anchor
	Raw Material	PEEK CF as per ASTM F3333 and UHMWPE Suture as per ASTM F2848.

AC Joint Button

S.No.	Device Name	AUXILOCK® AuxFix Button (AC Joint), AUXILOCK® AC Joint Kit
21, 22.	Picture	 

	Code	Description
	6-037-01	AUXILOCK® AuxFix Button (AC Joint)
	6-041-02	AUXILOCK® AC Joint Kit
	Raw Material	Titanium Alloy as per ISO 5832-3/ASTM F136 and UHMWPE Suture as per ASTM F2848.

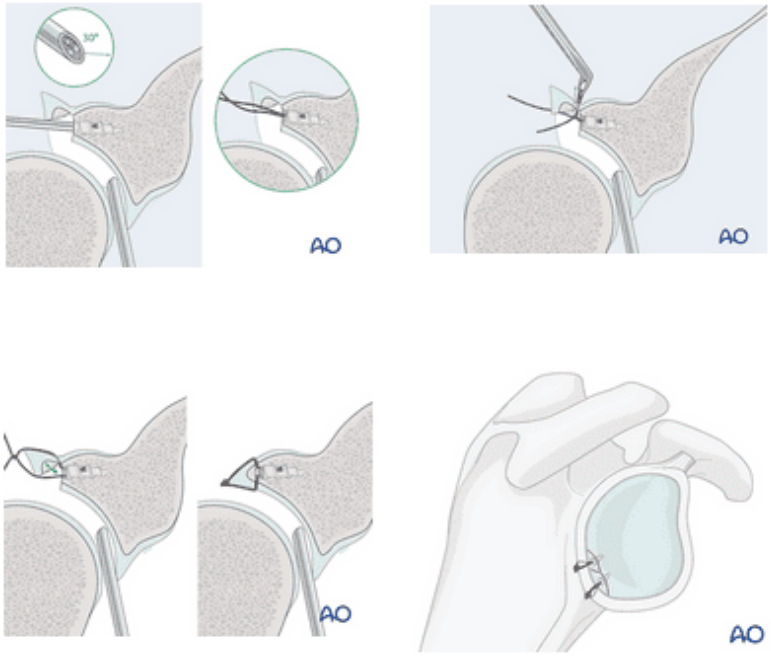
Gyrolock PEEK OPTIMA Knotless Screw In Anchor		
S.No.	Device Name	Gyrolock PEEK OPTIMA Knotless Screw In Anchor, Gyrolock SP PEEK OPTIMA Knotless Screw In Anchor
23, 24.	Picture	
	Code	Description
		GYROLOCK PEEK OPTIMA Knotless Screw In Anchor
	6-052-01	AUXILOCK® Gyrolock 3.5mm x 15.8mm Knotless PEEK OPTIMA Screw-In Anchor

	6-052-02	AUXILOCK® Gyrolock 4.75mm x 22.5mm Knotless PEEK OPTIMA Screw-In Anchor
	6-052-03	AUXILOCK® Gyrolock 5.5mm x 22.5mm Knotless PEEK OPTIMA Screw-In Anchor
		GYROLOCK SP PEEK OPTIMA Knotless Screw In Anchor
	6-052-04	AUXILOCK® Gyrolock SP 4.75mm x 24.5mm Knotless PEEK OPTIMA Screw-In Anchor, Self-Punching
	6-052-05	AUXILOCK® Gyrolock SP 5.5mm x 24.5mm Knotless PEEK OPTIMA Screw-In Anchor, Self-Punching
	Raw Material	PEEK OPTIMA as per ASTM F2026 and UHMWPE Suture as per ASTM F2848.

Other details of AUXILOCK Shoulder Arthroscopy System:

Device Compliance to regulation		We are proposing the AUXILOCK Shoulder Arthroscopy System as per the compliance to European Union Medical Device Regulation (EU MDR 2017/745).
1.	DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES	
1.1	Device Description and Specification	
	Product/Trade Name	Auxein AUXILOCK Shoulder Arthroscopy System
	General Description	AUXILOCK® Shoulder Arthroscopy system includes Suture Anchor devices. The suture anchors are recommended for use in both large and small joint soft tissue repairs in arthroscopic, mini open or open surgeries. The AC Button can be use in Acromioclavicular joint repair during arthroscopic or open surgeries. There are various types of devices included in the shoulder Arthroscopy system which are as follows: Titanium Screw-in Anchor with NeedleTitanium Screw-in Anchor without NeedlePEEK OPTIMA Screw In Anchor With NeedlePEEK CF Screw In Anchor With NeedlePEEK OPTIMA Screw In Anchor Without NeedlePEEK CF Screw In Anchor Without NeedlePEEK OPTIMA AuxPik Suture-Based AnchorPEEK CF Knotless Anchor with DriverPEEK CF Knotless Anchor without DriverRotador PEEK CF Screw In Knotless AnchorPEEK CF Push In Anchor Without NeedlePEEK CF Push In Anchor with NeedleRotador PEEK OPTIMA Screw In Knotless AnchorPEEK OPTIMA Knotless Anchor with DriverPEEK OPTIMA Knotless AnchorPEEK OPTIMA Push In Anchor without NeedlePEEK OPTIMA Push In Anchor with NeedleAuxsuture Anchor without NeedleAuxsuture Anchor with NeedlePEEK

		OPTIMA Tendo Screw-In AnchorPEEK CF Tendo Screw-In AnchorAC Joint ButtonGyrolock PEEK OPTIMA Knotless Screw In AnchorGyrolock SP PEEK OPTIMA Knotless Screw In Anchor
	Intended Purpose	The AUXILOCK Shoulder Arthroscopy System is indicated for use in the fixation of muscles, ligaments and tendon in patients requiring muscle, ligament or tendon repair.
	Intended Users	The AUXILOCK Shoulder Arthroscopy System is recommended to be used by only well-trained, certified and experienced surgeons.
b.	Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.
	Medical Conditions to be diagnosed, treated and/or monitored	AUXILOCK Shoulder Arthroscopy System is used to reconstruction or repair the muscles, ligaments or tendon of the shoulder joint.
	Patient Selection Criteria	**Inclusion criteria** Male or Female, aged between 18 to 75 years and skeletally mature patient. **Exclusion criteria** Subjects with a disease entity or condition that could hinder healing and create unacceptable risk of fixation failure or complications such as known active cancer, neuromuscular disorder etc.In case, subject has inadequate tissue coverage of the operative site.Subjects with mental disordersFemale participant who is pregnant or planning pregnancy during the course of the study.
c.	Principles of Operation Mode of Action	This procedure may be performed with the patient in either a prone position or lateral decubitus position. Posterior fragments are reduced and fixed through a posterior arthroscopic instrument portal with the camera inserted anteriorly. If the surgeon is not familiar with an arthroscopic approach, the posterior approach may be used. The suture anchor is inserted through the fracture line into the bone. The anchors need to be placed sufficiently deep so that the metal/polymer part does not protrude above the fracture. In repairing the

		labrum, the anchor is placed as close as possible to the articular margin. Once the anchor is securely seated in bone, the handle is removed. An appropriately angled suture passer is used to shuttle one suture through the labrum. The sutures are then tied and as the knot is tightened, the fracture is reduced. The procedure is repeated for any other fragments not suitable for screw fixation. At the end of any procedure, use the image intensifier to check the placement of fixation devices and the reduction of the joint.
	Scientifically demonstration of Principle of Operation	
d.	Rationale for considering as a Medical device	As per Article 2 (1) of EU MDR 2017/745 'Medical Device' means any instruments, apparatus, appliance, software, implant, reagent, material or

		other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: *Thus, AUXILOCK Shoulder Arthroscopy System is an implant used in humans for medical purposes to treat the tear of ligaments and Tendon.* Applicable/Non-Applicable defines applicancy of the statement: a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease- **Not Applicable** ***Rationale for Non Applicability*** The AUXILOCK Shoulder Arthroscopy System is an implant used for the treat the tear of muscle, ligaments and Tendon. Thus, it is not used for diagnosis, prevention, monitoring, prediction, prognosis or alleviation of disease. b) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability- **Applicable** ***Rationale for Applicability*** The AUXILOCK Shoulder Arthroscopy System is an implantable device used for the treat the tear of muscle, ligaments and Tendon. c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state- **Not Applicable** ***Rationale for Non Applicability***

		The AUXILOCK Shoulder Arthroscopy System is intended to treat the tear of muscle, ligaments and Tendon.. The device is not meant for investigation, replacement or modification of the anatomy or of a physiological or pathological state purpose of use. d) providing information by means of in vitro examination of specimens derived from the human body, including organs, blood and tissue donations- **Not Applicable** ***Rationale for Non Applicability*** AUXILOCK Shoulder Arthroscopy System is made up of metal/Polymer and employed to fix the tear of muscle, ligaments and Tendon. This system does not contain the In-vitro examination of specimens derived from the human body, including organ, blood and tissue donations. Moreover, the device does not achieve its principal intended action by any pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Hence, the AUXILOCK Shoulder Arthroscopy System is considered to be a medical device. The following products shall also be deemed to be medical devices: e) Devices for the control or support of conception- **Not Applicable** ***Rationale for Non Applicability*** The AUXILOCK Shoulder Arthroscopy System used to treat the tear of muscle, ligaments and Tendon. This device is not for the control or support of conception. f) Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in

		Article 1(4) and of those referred to in the first paragraph of this point- **Not Applicable** ***Rationale for Non Applicability*** The AUXILOCK Shoulder Arthroscopy System is intended for the fixation of muscle, ligaments and Tendon. The system is not meant for cleaning, disinfection or sterilization of device.
e.	Novel Features	The AUXILOCK Shoulder Arthroscopy System comprises of already existing devices approved in EU market under the regulation MDD 93/42/EEC. Since the device was placed on the market, there are no changes or modifications in device related to raw material, design, manufacturing process (coolants, lubricants, chemicals), intended use, post processing, etc.
f.	Description of key functional elements	The AUXILOCK Shoulder Arthroscopy System comprises of : AnchorSutureNeedleAnchor are used with accessories for fixation of muscle, ligament and tendon tears. The description of the components used with anchors to preserve intra articular structure are enlisted below: ***Suture*** The suture helps in stitching and holding muscles, ligaments, tendons together after a surgery. ***Needle*** To place the sutures within the tissues. Needles are designed to penetrate muscle and fascia.
g.		
	Sterility	All Products covered in AUXILOCK Shoulder Arthroscopy System are supplied in Sterile state. The Sterile implants which are placed on the market are sterilized by using EO Sterilization (SAL 10^{-6}).
	Radioactivity	Products covered in AUXILOCK Shoulder Arthroscopy System are metal products and does not emit any ionizing or non-ionizing radiation.
	Category	Non-Active, Implantable, Long term, Surgically Invasive Device.

	Use	For Single Use only
	Contact Duration	Long Term, intended for continuous use for more than 30 days (classified as per EU MDR 2017/745 as amended).
	MRI Compatibility	The AUXEIN MEDICAL AUXILOCK Shoulder Arthroscopy System have not been evaluated for safety and compatibility in the MR environment. The AUXEIN MEDICAL implants have not been tested for heating or migration in the MR environment. Patients should seek the opinion of medical experts before entering the MRI (Magnetic Resonance Imaging) environment.
1.2	Reference to Previous and Similar Generations of the device	
a.	CE Mark (Legacy device)	CE Approved by DNV (2460) under MDD 93/42/EEC Certificate No. 10000434275-PA-NA-IND Rev. 0.0
	USFDA clearance	Yes (AUXILOCK Shoulder Arthroscopy System are cleared by USFDA whose details are as follow:) 510(k) Number: K213110, K213109, K213104
b.	Similar devices available in Union or international market.	The Similar devices available in the Union or International Market enlisted below: Smith & Nephew: TWINFIX Suture Anchors (2797) Arthrex Inc: AC TightRope®, SwiveLock® Anchor (CE 2797) Depuy Mitek: Healix Advance™ family (CE 0086) Parcus (Anika): Draw Tight™ Suture-Based Anchors, PEEK CF Push-In Suture Anchors, V-LoX & V-LoX³ Titanium Screw-In Suture Anchors, MiTi & MiTi XL Titanium Screw-In Suture Anchors, Knotless PEEK CF Push-In Suture Anchors (CE 2797)

Measurable safety and performance parameters

- Measure the VAS, ASES, WOSI Scores
- Record of any adverse event, serious adverse event and complication

4. Information on any residual risks and any undesirable effects, warnings and precautions.

Residual risks and undesirable effects

A listing of potential adverse events includes, but is not limited to:

Infection, both deep and superficial.Allergies and other reactions to device materials.Risks due to anesthesia.

Quantitative based risk is evident

Safety Parameters	Article No.	No. of Patients having Adverse Events	Percentage of Patients (%)
Cramping	5	3	4.34
Reoperation, Revision CC ligament, Hardware removal, Infection/incision and drainage, Adhesive capsulitis, Fracture	7	23	44.0
superficial infections, pain	9	5	23

Warning & Precautions:

- This product should only be used by or on the order of a surgeon.
- The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
- Any decision to remove the device should consider the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
- The patient should be advised of the use and limitations of this device.
- Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
- This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross- contamination leading to patient infection.
- This device must never be re-sterilized.
- Appropriate instrumentation should be used to implant this device.

5. The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Prospective Clinical Data (PMCF Study):

Prospective Study and Retrospective Study of the legacy device has been approved by the ethics committee.

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_41	Ongoing	INDIA	46/80	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of AUXILOCK® Shoulder Arthroscopy System.					
Number of study sites	Three					
No. of Patients enrolled	46					

Study design: Shoulder Arthroscopy study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. It is a Prospective; Multi- Centric, Interventional, Longitudinal Study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events, events specific to defined subject populations, or the performance of the device in a more diverse population of the subjects with Shoulder injuries.

Inclusion criteria

Documented evidence of shoulder injuries; Rotator Cuff, Bankart Lesion, Tenodosis and AC Joints etc. (i.e., MRI Report).Male or Female, aged between 18 to 75 years.Subject scheduled for Shoulder arthroscopic surgery.

Exclusion criteria

Subjects having any Local active infection.Blood supply limitations or other systemic conditions that may Retard healing.Subjects having Foreign body sensitivity.Insufficient quality or quantity of bone.Subjects who are incarcerated or have pending incarceration.Female participant who is pregnant or planning pregnancy during the study.

Primary Objective

1. To calculate mean time in achieving full weight lifting capacity of the affected shoulder.
2. To assess the improvement in functional scores; American Shoulder and Elbow Score (ASES) and Western Ontario Shoulder Instability (WOSI) following the shoulder arthroscopic surgery.

Secondary Objective

To assess the improvement in Visual Analogue Scale (VAS) score following the shoulder arthroscopic surgery.Evaluation of safety of the device by recording any Adverse Events (AE), Serious Adverse Events (SAE).

Primary Endpoints

3. Time taken to achieve full weight lifting capacity.
4. Evaluation of functional scores; ASES and WOSI following the arthroscopic surgery. [Visits: Baseline 2, 6 weeks, 3, 6 and 12 months]

Secondary Endpoints

5. Evaluation of shoulder pain by VAS following arthroscopic surgery. [Visits: Baseline 2, 6 weeks, 3, 6 and 12 months].
6. Assessment of device related of AE, and SAEs.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristic	**Age (years)**	**Weight (kg)**	**Height (cm)**	**Body Mass Index (kg/m2)**
Mean (n=46)	40.1±16.0	62.5±7.7	163.5±10.4	24.58±3.50

Gender distribution of study subjects

Male	30/46 (65.21%)
Female	16/46 (34.78%)

Total patients	6 weeks follow up	3 months follow up	6 months follow up	12 months follow up
76 (Prospective study: 46 pts) Retrospective study: 30 pts)	35/36	24/26	16/18	4/5

Pain and functional scores of patients at baseline and follow up visits

Scores	**Baseline(n=46) (a)**	**6 weeks follow up(n=35) (b)**	**3 monthsfollow up(n=24) (c)**	**6 monthsfollow up(n=16) (d)**	**12 monthsfollow up (n=04) (e)**	**Statistical significance (P value)**
VAS Score	7.9±0.9	5.0±1.3	3.7±1.7	3.7±1.4	2.25±0.5	a vs. b<0.001a vs. c<0.001a vs. d<0.001a vs. e NA

ASES	22.7±11.5	49.3±18.0	67.3±22.4	67.9±20.2	73.4±8.7	a vs. b<0.001a vs. c<0.001a vs. d<0.001a vs. e NA

Study Method

The PMCF study have been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI has designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study aimed to recruit a total of 80 subjects, who meet Inclusion and Exclusion criteria as per the protocol. Subjects are followed at a stipulated time frame i.e. 6 weeks, 3 months, 6 months and 12 months after surgery.

PMCF: Shoulder Arthroscopy study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. It is a Prospective; Multi- Centric, Interventional, Longitudinal Study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events, events specific to defined subject populations, or the performance of the device in a more diverse population of the subjects with Shoulder injuries.

All statistical tests will be conducted at two-sided 5% significance level, unless indicated otherwise. The primary and secondary endpoints will be summarized using descriptive statistics (Mean, Median, ± Standard Deviation, Minimum, Maximum). Categorical data of endpoint will be summarized using frequency count (n) and percentages (%). The change from screening will be calculated and summarized using descriptive statistics (Mean, Median ± Standard Deviation, Minimum, Maximum) along with confidence intervals. Data will be checked for normality. For a normal distribution, parametric tests will be applied; otherwise equivalent non-parametric tests will be applied for analysis. For normally distributed data, intra group at various follow-up using Paired-t-test using the statistical software. P value of ≤ 0.05 to be considered as statistically significant.

Study Result

The interim analysis of data of 46 patients recruited in the study so far provides significant information with respect to implants safety and performance. Study key findings are; substantial improvement in pain score and function scores, and no occurrence of serious adverse events.

The substantial reduction in VAS score indicates that the intervention effectively alleviate pain in study population. This is particularly important as pain levels at baseline were found to be high, indicating that the intervention positively impacts the patients quality of life. Furthermore, the increase in functional score; ASES highlights the effectiveness of the intervention. Findings of the interim report shows that Shoulder arthroscopy system manufactured by Auxein Medical Private Limited is safe for the use in patient and perform the intended function.

Conclusion

The study of clinical data of patients enrolled in the study so far provides valuable insights into the safety and performance of the implants. Key findings include a significant improvement in pain and functional scores, with no serious adverse events reported. The notable reduction in the Visual Analog Scale (VAS) score demonstrates that the intervention effectively alleviates pain in the study population. This is particularly significant given the high baseline pain levels, indicating a positive impact on patients' quality of life. Additionally, the improvement in the functional score, as measured by ASES, further underscores the intervention's effectiveness. The findings of this interim report confirm that the shoulder arthroscopy system developed by Auxein Medical Private Limited is both safe for patient use and effective in achieving its intended purpose

6. Possible diagnostic or therapeutic alternatives.

Diagnosing a shoulder injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan or arthroscopy. Both non-operative and surgical treatment options are available to treat shoulder pain and problems depending on the type and severity of the condition.

Non-Surgical Treatment	**Surgical Treatments**
Medications Cortisone InjectionsPlatelet-Rich-Plasma, Stem-Cell TherapyPhysical Exercise	Suture Anchors

7. Suggested profile and training for users.

The intended user (surgeon) should be well-qualified and must have gained sufficient training regarding the use of the device and should have experience in trauma surgery. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).

8. Reference to any harmonized standards and CS applied.

The following harmonized standards and guidance documents are applicable on AUXILOCK Shoulder Arthroscopy System:

Harmonized Standards		
S. No.	**Standard Designation**	**Title of Standard**
1.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
2.	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021).
4.	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5.	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
6.	EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
7.	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
8.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
9.	EN ISO 11737-1:2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

10.	EN ISO 11737-2:2020	Sterilization of health care products -Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
11.	EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020).
12.	EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)

Non Harmonized Standards	
Standard	**Description**
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015/Amd 1:2020	Medical devices - Application of usability engineering to medical devices
ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good Clinical Practice.
ISO 14602:2010	Non-active surgical implants - Implants for osteosynthesis - Particular Requirements.
ISO 14630:2024	Non-active surgical implants - General Requirements
ISO 14644-1:2015	Clean-rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.
ISO 14644-2:2015	Clean-rooms and associated controlled environments - Part 2: Monitoring to provide evidence of clean-room performance related to air cleanliness by particle concentration.
ISO 14644-3:2019	Clean-rooms and associated controlled environments - Part 3: Test Methods.
ISO 14644-4:2022	Clean-rooms and associated controlled environments - Part 4: Design, construction and start-up.
ISO 14644-5:2025	Clean-rooms and associated controlled environments - Part 5: Operations
ISO 14644-7:2004	Clean-rooms and associated controlled environments - Part 7: Separative devices (clean air hoods, glove boxes, Isolators and mini).
ISO 14644-8 :2022	Clean-rooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical

	concentration (ACC).
ISO 14644-9 :2022	Clean-rooms and associated controlled environments – Part 9: Classification of surface cleanliness by particle concentration.
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-2: 2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 5832-3:2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2021)
ISO 7153-1:2016	Surgical Instrumets------ Materials
ASTM F136-13 (2021)e1	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F2026-17	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
ASTM F3333-20	Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
ASTM F899-20	Standard Specification for Wrought Stainless Steels for Surgical Instruments
ASTM F2848-17	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns
ASTM D4169-22	Standard Practice for Performance Testing of Shipping containers and System.
ASTM 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 19227:2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements

ISO/TR 10993-33:2015	Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3.

MDCG Guidelines	
Guidance Documents	**Description**
MDCG 2023-7	Practical Application of Article 61(4)
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2020-13	Clinical Evaluation Assessment Report Template
MDCG 2020-8	Guidance on PMCF evaluation report template
MDCG 2020-7	Guidance on PMCF plan template
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2019-9, Rev.01	Summary of safety and clinical performance
MDCG 2019-5	Registration of legacy devices in EUDAMED
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2018-2	Future EU medical device nomenclature - Description of requirements
MDCG 2021-11	Guidance on Implant Card –‘Device types’
MDCG 2022-16	Guidance on Authorized Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746
MDCG 2022-9	Summary of safety and performance template
MDCG 2019-14	Explanatory note on MDR codes
MDCG 2021-19	Guidance notes integration of the UDI within an organisation’s quality management system
MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR
MDCG 2018-1, Rev. 04	Guidance on BASIC UDI-DI and changes to UDI-DI

MDCG 2021-25	Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC
MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022
MEDDEV 2.7/1 revision 4, 2016	Clinical Evaluation: A guide for manufacturers and notified bodies.

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
00	04-09-2024	Initial Release	YesValidation language: No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
01	23-11-2024	Update as per the finding receive on LOF 1	YesValidation language: No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
02	10-12-2024	WOSI score is added	YesValidation language: No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
03	30-06-2025	Updated the PMCF Data	YesValidation language: No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
04	04-11-2025	Updated the Basic UDI-DI	YesValidation language:

			No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
05	06-11-2025	Updated the Basic UDI-DI	YesValidation language: No(only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

A summary of the safety and clinical performance of the device, intended for patients, is given below

Document revision: 05
Date issued: 06-11-2025

Device identification and general information

Device Trade Name: AUXILOCK Shoulder Arthroscopy System
Manufacturer Name: Auxein Medical Private Limited
Manufacturer Address: Plot No. 168-169-170, Phase-IV, Sector-57, Kundli, HSIIDC, Industrial Area, Sonipat, Haryana 131028, India
Basic UDI-DI: Titanium Screw-in Anchor with Needle-08903993SAAT006PJ, Titanium Screw-in Anchor without Needle-08903993SAATN006ZR, PEEK OPTIMA Screw In Anchor Without Needle-08903993SAAPO006YL, PEEK OPTIMA Screw In Anchor With Needle-08903993SAAPON006HU, PEEK OPTIMA AuxPik Suture-Based Anchor-08903993SAAPOS006JX, PEEK OPTIMA Knotless Anchor with Driver-08903993SAAPOKD00673, PEEK OPTIMA Knotless Anchor-08903993SAAPOK006H7, PEEK OPTIMA Push In Anchor without Needle-08903993SAAPOP006JA, PEEK OPTIMA Push In Anchor with Needle-08903993SAAPOPN006AY, Gyrolock PEEK OPTIMA Knotless Screw In Anchor-08903993SAAPOG006GB, Gyrolock SP PEEK OPTIMA Knotless Screw In Anchor-08903993SAAPOGS0068Y, Rotador PEEK OPTIMA Screw In Knotless Anchor-08903993SAAPOR006JQ, PEEK OPTIMA Tendo Screw-In Anchor-08903993SAAPOT006K6, PEEK CF Screw In Anchor Without Needle-08903993SAAPC006VY, PEEK CF Screw In Anchor With Needle-08903993SAAPCN006DQ, Rotador PEEK CF Screw In Knotless Anchor-08903993SAAPCR006EL, PEEK CF Tendo Screw-In Anchor-08903993SAAPCT006F2, PEEK CF Knotless Anchor with Driver -08903993SAAPCKD00627, PEEK CF Knotless Anchor without Driver-08903993SAAPCK006D3, PEEK CF Push In Anchor with Needle-08903993SAAPCPN00664, PEEK CF Push In Anchor without Needle-08903993SAAPCP006E6, Auxsuture Anchor without Needle-08903993SAAU006PR, Auxsuture Anchor with Needle-08903993SAAUN00627, AC Joint Button-08903993SABT006PV
Year when the device was first CE-marked: 2021

Intended use of the device

Intended Purpose	The AUXILOCK Shoulder Arthroscopy System is indicated for use in the fixation of muscles, ligaments and tendon in patients requiring muscle, ligament or tendon repair.
Indications of Use	The AUXILOCK Shoulder Arthroscopy System is indicated for use in Bankart lesion repairs, SLAP lesion repairs, Acromioclavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsulolabral reconstructions, Biceps tenodesis, and Deltoid Repairs.
Contraindications	Contraindications may be relative or absolute. The conditions listed below may preclude or reduce the chance of a successful outcome: Any case not described in the indications.In patients where there is a possibility for conservative treatment.Active, suspected or latent infection in the affected area.SepsisInsufficient quantity or quality of bone, osteoporosisBlood supply limitations or other systemic conditions that may retard healing.Fever or leukocytosis.Foreign body sensitivity, if suspected.
Intended Patient Population	Male or Female, aged between 18 to 75 years and skeletally mature patient.

Device description

AUXILOCK® Shoulder Arthroscopy system includes Suture Anchor devices. The suture anchors are recommended for use in both large and small joint soft tissue repairs in arthroscopic, mini open or open surgeries. The AC Button can be use in Acromioclavicular joint repair during arthroscopic or open surgeries. The details regarding AUXILOCK Shoulder Arthroscopy System and screws can be found at **www.auxein.com**.

The more details regarding these AUXILOCK Shoulder Arthroscopy System are mentioned below:

Parameter	**Details**	**Certified By**	**Certificate Number**
Legacy Device	Yes, AUXILOCK Shoulder Arthroscopy System (Certified under MDD 93/42/EEC)	DNV Product Assurance AS	10000434275-PA-NA-IND Rev. 0.0
Material/substances in contact with patient tissues	The Raw Materials used for manufacturing the Implants consists of Titanium Alloy (Ti-6Al-4V) as per ISO 5832-3:2021, PEEK OPTIMA as per ASTM F2026 and PEEK CF as per ASTM F3333, Stainless Steel as per ISO 7153-		

	1:2016 and UHMWPE Yarn/Suture (BioBraid) as per ASTM F2848.
USFDA Cleared	Yes (AUXILOCK Shoulder Arthroscopy System are approved by USFDA whose details are as follow:) 510(k) Number: K213110, K213109, K213104
Risk Class	IIb (According to the EU Regulation 2017/745 (MDR) Annex VIII Rule 8)
Authorized Representative Name and Address	Name: CMC Medical Devices & Drug S.L Address: 29015 Málaga, Spain
Notified Body Name and Single Identification Number	Name: DNV Product Assurance AS Single Identification Number: 2460

Principle of operation

This procedure may be performed with the patient in either a prone position or lateral decubitus position. Posterior fragments are reduced and fixed through a posterior arthroscopic instrument portal with the camera inserted anteriorly. If the surgeon is not familiar with an arthroscopic approach, the posterior approach may be used.

The suture anchor is inserted through the fracture line into bone. The anchors need to be placed sufficiently deep so that the metal/polymer part does not protrude above the fracture. In repairing the labrum, the anchor is placed as close as possible to the articular margin. Once the anchor is securely seated in bone, the handle is removed. An appropriately angled suture passer is used to shuttle one suture through the labrum. The sutures are then tied and as the knot is tightened, the fracture is reduced. The procedure is repeated for any other fragments not suitable for screw fixation. At the end of any procedure, use the image intensifier to check the placement of fixation devices and the reduction of the joint.

Description of Key functional elements:

The AUXILOCK Shoulder Arthroscopy System comprises of :
AnchorsSutureNeedle
Anchor are used with accessories for fixation of muscle, ligament and tendon tears. The description of the components used with anchors to preserve intra articular structure are enlisted below:

Suture

The suture helps in stitching and holding muscles, ligaments, tendons together after a surgery.

Needle

To place the sutures within the tissues. Needles are designed to penetrate into muscle and fascia.

Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

The potential risks that arise regarding the device are controlled using risk mitigation method and conveying those risk to the patients from surgeon.

A listing of Remaining Risk and undesirable effects includes, but is not limited to:
Infection, both deep and superficial.Allergies and other reactions to device materials.Risks due to anesthesia.

Warning & Precautions:

1. This product should only be used by or on the order of a surgeon.
2. The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
3. Any decision to remove the device should consider the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
4. The patient should be advised of the use and limitations of this device.
5. Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
6. This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross- contamination leading to patient infection.
7. This device must never be re-sterilized.
8. Appropriate instrumentation should be used to implant this device.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

Till now, regarding Auxein's AUXILOCK Shoulder Arthroscopy System there is no FSCA.

Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device

Description and consequences

The shoulder joint is structurally classified as a synovial ball-and-socket joint and functionally as a diarthrosis and multiaxial joint. It involves an articulation between the glenoid fossa of the scapula (shoulder blade) and the head of the humerus (upper arm bone). Due to the very loose joint capsule, that gives a limited interface of the humerus and scapula, it is the most mobile joint of the human body.

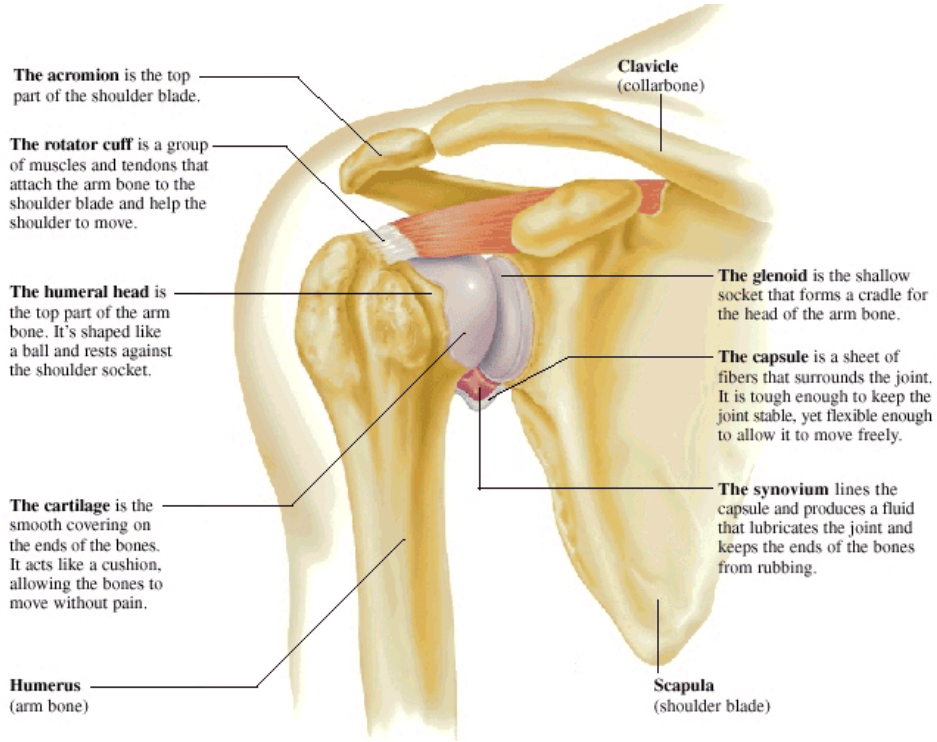


Figure: Shoulder joint

Common Causes of Shoulder Injuries

Whether throwing a ball, paddling a canoe, lifting boxes, or pushing a lawn mower, we rely heavily on our shoulders to do many activities. Normally, the shoulder has a wide range of motion, making it the most mobile joint in the body. But because of this flexibility, it's not very stable and is easily injured.

The shoulder is made up of two main bones: the end of the upper arm bone (humerus) and the shoulder blade (scapula). The end of the humerus is round and fits into a socket in the scapula. Surrounding the shoulder is a group of muscles and ligaments. Ligaments connect the bones of the shoulders. Tendons connect the bones to surrounding muscles.

To keep shoulders healthy and pain-free, it's important to know how to spot and avoid common injuries.

Shoulder instability

Shoulder instability happens most often in young people and athletes. When muscles and ligaments that hold it together are stretched beyond their normal limits, the shoulder becomes unstable. For younger people, this health problem may be a normal part of growth and development. Shoulders often stiffen or tighten with age.

In athletes, shoulder instability is caused by certain motions used in tackling or pitching, for example. These motions put great force on the shoulder, stretching the shoulder ligaments over time. It can cause pain that comes on either quickly or gradually, a feeling that the shoulder is loose, or a weakness in the arm. Treatment includes rest, physical therapy, or surgery.

A shoulder (or acromioclavicular) separation, or sprain, happens when the ligaments that hold the clavicle to the acromion tear. If this happens, the clavicle is pushed out of place and may form a bump at the top of the shoulder. Sprains often happen during a fall, when your hand or arm is outstretched to stop the fall, or when you fall on a hard surface. When the sprain happens, it causes severe pain, a misshapen shoulder, and decreased shoulder movement. Treatment depends on the severity of the sprain. To help ease pain and swelling, apply ice right after the injury. Keeping the arm in a sling to limit the movement of the shoulder lets ligaments heal. This is often followed by physical therapy exercises. Sometimes, surgery is needed.

If the ligaments holding the shoulder bones tear and can't hold the joint together, the shoulder is dislocated. Falling onto an outstretched hand, arm, or the shoulder itself, or a violent twisting, can cause a shoulder dislocation. The main symptom is pain in the shoulder that becomes worse with movement. To treat a dislocation, apply ice right after the injury to ease pain, swelling, and bleeding around the joint. Within 15 to 30 minutes of the injury, the joint will be painful and swollen. A dislocated shoulder needs urgent care. Healthcare providers treat dislocations by using gentle traction to pull the shoulder back into place. When the shoulder pops out of the socket repeatedly, it’s called recurrent instability. Recurrent instability can be treated with surgery to fix the torn ligaments.

Rotator cuff tear

The rotator cuff is a group of four muscles of the upper arm. They allow you to raise and rotate the arm. The muscles are attached to the bones by tendons. The tendons of the rotator cuff allow the muscles to move the arm. If the tendons tear, the humerus can't move as easily in the socket. This makes it hard to move the arm up or away from the body.

As people age and are less active, tendons start to degenerate and lose strength. This weakening can lead to a rotator cuff tear. Most rotator cuff injuries happen to middle-aged or older adults who already have shoulder problems. They can happen in younger people, too. The shoulder has a poor blood supply. This makes it harder for the tendons to fix and maintain themselves. Using your arm overhead puts pressure on the rotator cuff tendons. Repetitive movement or stress to these tendons can lead to impingement. This is when the tissue or bone in that area becomes misaligned and rubs or chafes.

The rotator cuff tendons can be injured or torn by trying to lift a very heavy object with an extended arm. It can also happen from falling, or by trying to catch a heavy falling object.

Symptoms of a torn rotator cuff include tenderness and soreness in the shoulder when using the shoulder. If the tendon has ruptured, you may not be able to raise the arm at all. It may be hard to sleep lying on that side. You may feel pain when pressure is put on the shoulder.

Treatment depends on the severity of the injury. If the tear is not complete, your healthcare provider may suggest RICE (rest, ice, compression, and elevation). Resting the shoulder is probably the most important part of treatment. But after the pain has eased, you will need to start physical therapy to regain shoulder movement. Your healthcare provider may prescribe a nonsteroidal anti-inflammatory drug (NSAID). These help ease pain and swelling. NSAIDs are the most common medicines used. Medicines may be prescribed or bought over the counter. They may be given as pills. Or they may be put on the skin as a gel, cream, or patch.

Frozen shoulder

This extreme stiffness in the shoulder can happen at any age. It affects about 1 in 50 Americans, most often between ages 40 and 60. The causes are not fully understood. Frozen shoulder can affect people with diabetes, thyroid disease, heart disease, or Parkinson disease. It can also happen if the shoulder has been immobile for a period of time. It can happen when a minor shoulder injury heals with scar tissue that affects how the joint moves. This scar tissue reduces flexibility in the shoulder and makes it more prone to injury. The main symptom is not being able to move the shoulder in any direction without pain. Treatment can be NSAIDs, cortisone shots, or physical therapy. You can reduce further injury and stiffness by stretching before starting activities.

Overuse/strains

A sudden increase in activity can place great stress on the shoulders and lead to a loss of flexibility. This is a common problem in middle age, especially among people who don't exercise regularly but go out every now and then for an intense sport. Although painful and inconvenient, overuse problems can often be treated with rest, NSAIDs, and stretching exercises.

Symptoms:

The shoulder's ball-and-socket joint gives you great range of motion, but it comes at the expense of stability. The shoulder joint gets dislocated more often than any other joint in the body. And repeated stress from the way you use your shoulders on the job or playing sports can lead to tears and other injuries.
You can treat some shoulder injuries at home for a few days with rest and ice. You can bandage it to hold it in place if necessary, and raise it above your heart. But some injuries need professional help. Here are signs that you need to see a doctor right away:

- Your shoulder joint looks deformed.
- You can’t use your shoulder at all.
- The pain is intense.
- Your shoulder swells suddenly.
- Your arm or hand is weak or numb.
- The pain comes with swelling, redness, or a fever.
- You have pain that lasts for more than 2 to 4 weeks.
- The skin around your shoulder becomes discolored.

Diagnosis

Your doctor will start with a physical exam to check for any structural problems and rule out anything that might involve your spine or neck. Next, they’ll test your range of motion to see how strong and flexible your shoulder is. That will involve moving your arms in various ways, like above your head, across your body, or behind you, and rotating it 90 or 180 degrees.
Your doctor also might recommend one or more imaging tests to get a closer look:

- X-rays. These can help your doctor find bone spurs, arthritis, and other bone-related causes of your shoulder pain.
- MRI scan. This uses radio waves and a powerful magnet to make detailed images of your shoulder.
- CT scan. This is a series of X-rays taken from different angles. When they’re put together, they can give your doctor a better look at what’s happening with your shoulder.
- Electromyography (EMG). This measures the electrical activity in your muscles to see if there are any problems with your nerves.
- Arthroscopy. This surgery lets a tiny fiber-optic camera show your doctor high-definition images of your shoulder. In some cases, your doctor may also be able to treat the problem during the procedure.
- Arthrogram. This is an imaging test (CT, fluoroscopy, MRI, or ultrasound) done with an injected dye. First, the dye is injected into your joint, where it is absorbed to make it easier for the radiologist to see any problems in your shoulder’s tissues.

Pain Management

For dislocations, separations, and fractures, you need a doctor's help to get your shoulder back in the right position and then a sling to hold it in place while it heals. For many other issues, your doctor may suggest rest, heat or ice, and a medicine like aspirin or ibuprofen to reduce the pain and swelling. If your shoulder doesn't improve after these first steps, your doctor may try injecting a corticosteroid (an anti-inflammatory medicine) straight into the joint to relieve swelling and pain. Sometimes, cartilage tears, rotator cuff tears, and frozen shoulders don't improve with rest and medicine. Your doctor may recommend surgery. With any problem in your shoulder, your treatment plan will probably include exercises to help you stretch and strengthen the joint and to improve your range of motion.

Rehabilitation and Return to Activity

Non-operative rehabilitation

When designing a rehabilitation program for patients with an unstable shoulder (glenohumeral joint instability), it's important that the follow key factors should be considered:

- Onset of pathology
- Degree of instability and the effect of their functions
- Frequency of dislocation (chronic versus acute)
- Direction of instability (posterior, anterior or multidirectional)
- Concomitant pathologies (Bankart lesion, Hill sachs lesion, a reverse Hill sachs lesion)
- End range neuromuscular control
- Activity level

When considering all of this seven key factors, each patient will have a different structure of the non-operative rehabilitation program. This rehabilitation program will be divided into two categories: traumatic and atraumatic. It's important to discuss about this traumatic and atraumatic dislocation protocol, to make it better.

Traumatic

This traumatic dislocation protocol will vary in length for individual depending on the seven key factors and the arm dominance, desired goals and activities.

Phase 1 - The acute motion phase

The glenohumeral joint will be immobilized in an internally rotated and adducted position (2-4 weeks to allow scarring of the injured capsule and younger people 7-14 days). There is some discussion about the position of immobilization. Several studies concluded that immobilization in external rotation significantly reduced the recurrence rate of instability in first-time-dislocaters and chronic dislocation. The goals of this phase are: decrease pain, inflammation and muscular spasms; re-establish dynamic stability and non-painful range of motion; retard muscular atrophy; improve proprioceptive and protect the healing capsular structures. To achieve these goals, the following aspects will be implemented:

- decrease pain and inflammation
- Range of motion (ROM) exercise: activo-passive, passive and active with some help
- Strengthening/proprioceptive exercises: isometrics performed with the arm at side
- Rhythmic stabilization

Before the patient may enter the following phase, he must meet certain criteria which include:

7. Full functional ROM,
8. minimal pain and diminished inflammation,
9. sufficient static stability and
10. adequate neuromuscular control.

Phase 2 - Intermediate phase

Goals of this phase are: enhance the proprioceptive, kinesthesia and dynamic stabilization; regain and improve muscular strength and the neuromuscular control; and normalize arthrokinematics. To achieve these goals, the following aspects will be implemented:

- Progress ROM at 90 degrees abduction (pain free)
- Initiate isotonic strengthening: emphasis on external rotation and scapular strengthening
- Neuromuscular control of the shoulder complex: initiating proprioceptive exercise, rhythmic stabilization drills
- As needed: continue use of ice, eletrotherapy modalities

Before the patient may enter phase 3, he must meet certain criteria which include:

11. minimal pain and tenderness,
12. symmetrical capsular mobility,
13. full non-painfull ROM and
14. good strength, endurance and dynamic stability of the upper extremity and scapulothoracic musculature.

Phase 3 - Advances strengthening phase

Goals of this phase are: improve the neuromuscular control, strength, power and endurance; enhance the dynamic stabilization; and prepare the patient or athlete for his activities. To achieve these goals, the following aspects will be implemented:

- As needed: continue use of ice or electrotherapy modalities
- Continue isotonic strengthening, but now progressing resistance

- Emphasize PNF (45, 90 and 145 degrees)
- When working with athletes: advanced neuromuscular control drills
- Endurance training: increase the length of an exercise, more repetitions, more exercise periods throughout a day
- Initiate plyometric training

Before the patient may enter phase 4, he must meet certain criteria which include:

15. Full functional ROM,
16. static and dynamic stability and
17. sufficient strength and endurance.

Phase 4 - Return to activity phase

Goals of this phase are: increase the activity level (progressively) to prepare the patient or the athlete for functional return to his activity or sport. To achieve these goals, the following aspects will be implemented:

- Exercise as in phase 3
- Progress the isotonic strengthening exercises
- An interval sports program
- consider a brace for contact sports (stabilizing the glenohumeral joint)

Follow up:

- Isokinetic test (external and internal rotation; ab- and adduction)
- a progress interval training
- Maintain the exercise program

Clinical Evidence/Safety of the device

Prospective Clinical Evaluation

The summary of clinical evaluation and relevant information on post-market clinical follow-up.

Prospective Clinical Data (PMCF Study):

Prospective Study of the legacy device has been approved by the ethics committee.

Name or Code of Study	Completed (Yes/No)	Name of countries in study is conducted	No. of patients enrolled /and the target no.	No. of serious incidents	Serious incident rate (%)	No. of deaths
CR_PMCF/P_41	Ongoing	INDIA	46/80	0	0	0
Study Title	Post Market Clinical Follow-up (PMCF) study to evaluate the Safety and Performance of AUXILOCK® Shoulder Arthroscopy System.					
Number of study sites	Three					
No. of Patients enrolled	46					

Study design: Shoulder Arthroscopy study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. It is a Prospective; Multi- Centric, Interventional, Longitudinal Study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events, events specific to defined subject populations, or the performance of the device in a more diverse population of the subjects with Shoulder injuries.

Population Detail:

Summary of Demographics and Baseline Characteristics

Characteristics	Age (years)	Weight (kg)	Height (cm)	Body Mass Index (BMI)
Mean	40.1±16.0	62.5±7.7	163.5±10.4	24.58±3.50

Gender distribution of study subjects

Male	30/46 (65.21%)
Female	16/46 (34.78%)

Baseline and follow up details of patients

Total patients	6 weeks follow up	3 months follow up	6 months follow up	12 months follow up

76 (Prospective study: 46 pts) Retrospective study: 30 pts)	35/36	24/26	16/18	4/5

Pain and functional scores of patients at baseline and follow up visits

Scores	Baseline(n=46) (a)	6 weeks follow up(n=35) (b)	3 monthsfollow up(n=24) (c)	6 monthsfollow up(n=16) (d)	12 monthsfollow up (n=04) (e)	Statistical significance (P value)
VAS Score	7.9±0.9	5.0±1.3	3.7±1.7	3.7±1.4	2.25±0.5	a vs. b<0.001a vs. c<0.001a vs. d<0.001a vs. e NA
ASES	22.7±11.5	49.3±18.0	67.3±22.4	67.9±20.2	73.4±8.7	a vs. b<0.001a vs. c<0.001a vs. d<0.001a vs. e NA

Study Method

The PMCF study have been designed according to the applicable rules and regulation to collect evidence based scientific data. The Sponsor in association with PI has designed the study and obtained the approval from the Institutional Ethics Committee and the same has also been registered on CTRI. The study

aimed to recruit a total of 80 subjects, who meet Inclusion and Exclusion criteria as per the protocol. Subjects are followed at a stipulated time frame i.e. 6 weeks, 3 months, 6 months and 12 months after surgery.
PMCF: Shoulder Arthroscopy study is intended to answer specific questions relating to clinical performance, efficacy and safety (i.e. residual risks) of the device. It is a Prospective; Multi- Centric, Interventional, Longitudinal Study. The target population for this study is comprised of both males and females aged between 18 years to 75 years at the time of surgery. Study is designed to evaluate aspects related to issues with medium-term performance, the appearance of clinical events, events specific to defined subject populations, or the performance of the device in a more diverse population of the subjects with Shoulder injuries.

Study Result

The interim analysis of data of 46 patients recruited in the study so far provides significant information with respect to implants safety and performance. Study key findings are; substantial improvement in pain score and function scores, and no occurrence of serious adverse events.
The substantial reduction in VAS score indicates that the intervention effectively alleviate pain in study population. This is particularly important as pain levels at baseline were found to be high, indicating that the intervention positively impacts the patients quality of life. Furthermore, the increase in functional score; ASES highlights the effectiveness of the intervention. Findings of the interim report shows that Shoulder arthroscopy system manufactured by Auxein Medical Private Limited is safe for the use in patient and perform the intended function.

6. **Possible diagnostic or therapeutic alternatives**

Diagnosing a shoulder injury or problem includes a medical examination and usually the use of a diagnostic procedure(s) such as an x-ray, MRI, CT scan or arthroscopy. Both non-operative and surgical treatment options are available to treat shoulder pain and problems depending on the type and severity of the condition.

Non-Surgical Treatment	**Surgical Treatments**
MedicationsCortisone InjectionsPlatelet-Rich-Plasma, Stem-Cell TherapyPhysical Exercise	Suture Anchors

Suggested profile and training for users

The intended user (patient) should be have adequate knowledge regarding the device. The training materials i.e Surgical Technique, Instructions for Use, Catalog are already available on the manufacturer website (https://www.auxein.com/).